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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,242	09/27/2000	Leo G. Frenken	PM-271592/T3	8145
9629 7	590 01/19/2005	EXAMINER		
MORGAN LEWIS & BOCKIUS LLP			PONNALURI, PADMASHRI	
WASHINGTON, DC 20004			ART UNIT	PAPER NUMBER
			1639	
			DATE MAILED: 01/19/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
	09/626,242	FRENKEN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Padmashri Ponnaluri	1639				
The MAILING DATE of this communication a Period for Reply	appears on the cover sheet with	the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REI THE MAILING DATE OF THIS COMMUNICATIO - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a - If NO period for reply is specified above, the maximum statutory peri - Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may a reply reply within the statutory minimum of thirty (3 dod will apply and will expire SIX (6) MONTH tute, cause the application to become ABAN	y be timely filed 30) days will be considered timely. S from the mailing date of this communication. IDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 20	October 2004.					
· · · · · · · · · · · · · · · · · · ·	his action is non-final.					
3) Since this application is in condition for allow	· 					
Disposition of Claims						
4) ⊠ Claim(s) <u>1-4</u> is/are pending in the application 4a) Of the above claim(s) is/are without 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1-4</u> is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and	Irawn from consideration.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) a	0) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119	•					
12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the papplication from the International Bure * See the attached detailed Office action for a least	ents have been received. ents have been received in App riority documents have been re eau (PCT Rule 17.2(a)).	olication No ceived in this National Stage				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Sum					
 Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/Paper No(s)/Mail Date 		Mail Date rmal Patent Application (PTO-152)				

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/04 has been entered.

Status of Claims

3. Claims 5-9 were canceled and claims 1-4 are currently pending and are being examined in this application. Claim 1 has been amended by the amendment filed on 10/20/04.

Priority

- 4. This application is a national stage application of PCT/EP99/00481, filed on 1/25/99.
- 5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 7. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

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To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

The instant claims briefly recite 'an expression library comprising a repertoire of nucleic acid sequences (cloned from a non-immunized source), each nucleic acid sequence of said repertoire encoding at least part of variable domain of a heavy chain derived from an immunoglobulin naturally devoid of light chains, said at least part of the variable domain being sufficient to retain the ability to exhibit antibody bonding activity and wherein said library comprises approximately 10⁷ individual members with a high level of complexity.

The specification discloses that the invention is based on the unexpected finding that highly specific antibody fragments against a target antigen may be provided by screening an expression library comprising a repertoire of nucleic acid sequences. The specification discloses that a single 'one-pot' library of approximately 10⁷members with a high level of complexity. The library was screened for binding to RR-6 and dicarboxylic linoleic acid using a panning process. The specification discloses that after screening individual clones for specific binding activity to its antigen a large number of clones were identified, and these clones were shown to be highly active and exhibited strong antigen specific recognition. The example 1 of the specification discloses 'construction of naïve HC-V library.'

The specification does not disclose repertoire of nucleic acids encoding variable domain of heavy chain with high level of complexity. The specification discloses that the library comprising the repertoire is screened with specific antigens, RR-6 and dicarboxylic linoleic acid to identify the clones which are specific to the antigen. The library of repertoire of nucleic acids

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as claimed do not show the specificity without further screening. The property 'wherein said library comprises approximately 10⁷members with a high level of complexity was not disclosed in the specification. The specification has not disclosed a definition for high level of complexity. Since the disclosure is silent regarding what levels are considered as 'high level complexity', and no working examples of the library comprises approximately 10⁷ individual members with a high level of complexity, applicants are not in possession of the claimed library.

The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175).

Thus, the disclosure simply does not provide adequate support to show possession of the claimed invention. The disclosure is neither representative of the claimed genus (library), nor does it represent a substantial portion of the claimed genus. Moreover, the claimed library encompasses members which are yet to be prepared and the complexity ahs to be determined. This further evidences that instant disclosure does not constitute support for the claimed genus or a substantial portion thereof.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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9. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 10. The term "high level of complexity" in claim 1 is a relative term, which renders the claim indefinite. The term "high level of complexity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. It is not clear what does applicants mean high level of complexity, does applicants mean 'complexity' of the structure of the members, or the complexity of binding of the members to an antigen. And the specification has not defined the term, and further compared, which members the claimed library members have high level of complexity.
- 11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 5,800,988 (Casterman et al).

The instant claims briefly recite an expression library comprising a repertoire of nucleic acid sequences, each nucleic acid sequence encoding a part of variable domain of a heavy chain derived from an immunoglobulin naturally devoid of light chains, and wherein the library comprises approximately 10⁷ individual members with a high level of complexity.

Casterman et al (the '988 patent) disclose immunoglobulins devoid of light chains (refers to 'naturally devoid of light chains' of the instant claims). The reference discloses that the disclosed immunoglobulins comprise two heavy polypeptide chains sufficient for formation of a complete antigen binding site (i.e., see column 2, lines 32-33). The reference discloses that the disclosed immunoglobulins are further characterized by the fact that they are the product of the expression in a prokaryotic or in a eukaryotic host cell of DNA or of cDNA having sequence of an immunoglobulin devoid of light chains as obtainable from lymphocytes or other cells of camelids (i.e., see column 2, lines 35-40) (refers to the instant claims 1-4). The reference discloses cDNA libraries to isolate nucleic acid sequences coding for immunoglobulins of the invention (i.e., see column 11, lines 10-11). The reference discloses that the nucleic acid sequences of the disclosed immunoglobulins are used for the preparation of recombinant vectors and the expression of these sequences contained in the vectors by host cells (i.e., see column 11,

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lines 14-15). The reference discloses V_{HH} (variable heavy chain of immunoglobulin devoid of light chain) repertoire (refers to the repertoire of nucleic acid sequences of the instant claims) using DNA derived from an arbitrarily chosen tissue or cell type or V_{HH} repertoire using DNA obtained from B lymphocytes. The reference discloses in column 12, a cDNA library composed of nucleotide sequences coding for a heavy chain immunoglobulin by treating a sample containing lymphoid cells, especially from peripheral lymphocytes, spleen cells, lymph nodes or other lymphoid tissue from a healthy animal, especially selected from Camelids. The reference discloses that the preparation of the antibodies can also be performed without a previous immunization of Camelids (see column 14, lines 15-16) (refers to the 'non-immunized source' of the instant claims). The reference teaches that the cDNA was synthesized from camel spleen mRNA, which refers to the non-immunized source for cDNA.

The claimed invention differs from the prior art teachings by reciting that the library comprises approximately 10⁷ individual members with a high level of complexity. Since the instant claims do not recite how the expression vectors are structurally different from the reference expression vectors, and the instant specification discloses that the expression vectors are generated using conventional techniques, it would have been obvious to one skilled in the art to generate a library, which has approximately 10⁷ members. Further, the claimed expression library comprising repertoire of nucleic acid sequences encoding at least a part of a variable domain of a heavy chain naturally devoid of light chains, appear to be the same or obvious variations of the reference libraries, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the number of individual members with high complexity of the instant versus the

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reference method, which would result in patentably distinct compounds. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the reference library has different number of individual members with a high level complexity, as compared to the claimed library. See in re Best 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

15. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 584421 A1 (Casterman).

The instant claims briefly recite an expression library comprising a repertoire of nucleic acid sequences, each nucleic acid sequence encoding a part of variable domain of a heavy chain derived from an immunoglobulin naturally devoid of light chains, and wherein the library comprises approximately 10⁷ individual members with a high level of complexity.

EP 584421 A1 discloses immunoglobulins devoid of light chains. The immunoglobulins disclosed by the reference comprise two heavy chain polypeptide chains sufficient for the formation of a complete antigen binding site or several antigen binding site and devoid light polypeptide chains (refers to 'naturally devoid of light chains' of the instant claims) (i.e., see last paragraph in page 2). The reference discloses that the immunoglobulins can be isolated from animals, and are called 'heavy chain immunoglobulins. The reference discloses that the heavy chain immunoglobulins of the invention are secreted in blood of camelids (i.e., see page 3, lines 45). And the reference discloses methods for obtaining nucleotide sequences coding for all or part of the immunoglobulins, and the nucleotide sequences can be used for the preparation of recombinant vectors and the expression of these sequences contained in the vectors by host cells (refers to the instant claim 1) (i.e., see page 7). The reference discloses that the preparation of

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antibodies can also be performed without previous immunization of camelids. The reference discloses that V_H repertoire and libraries by cloning cDNA from lymphoid cells (i.e., see page 8). The reference discloses that in the method of obtaining cDNA library composed of nucleotide sequences encoding heavy-chain immunoglobulins, a sample containing lymphoid cells, especially peripheral, lymphocytes, spleen cells, lymph nodes or another lymphoid tissue from a healthy animal, especially selected among camelids (refers to cloned from a non-immunized source' of the instant claim) (i.e., see the example in page 8).

The claimed invention differs from the prior art teachings by reciting that the library comprises approximately 10⁷ individual members with a high level of complexity. EP 584421 Al discloses libraries of repertoire of nucleic acids encoding heavy chain immunoglobulins devoid of light chains. The individual members of the library of expression vectors comprising nucleic acid encoding heavy chain disclosed by the reference would have been same as the instant claims, because the instant specification discloses that the 'expression libraries according to the invention may be generated using conventional techniques described in EP-B-0368684 and EP-A-584421 (Casterman et al). Thus, the expression vectors of the instant claims are same as the reference expression vectors. Thus, the number of members in a library would be the same as the instant claims. The claimed number of members of the expression library comprising repertoire of nucleic acid sequences encoding at least a part of a variable domain of a heavy chain naturally devoid of light chains, appear to be the same or obvious variations of the reference library members, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the number of individual members with high complexity of the instant versus the

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reference method, which would result in patentably distinct compounds. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the reference library has different number of individual members with a high level complexity, as compared to the claimed library. See in re Best 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

16. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ghahroudi et al (FEBS Letters, 1997, page 521-526).

The instant claims briefly recite an expression library comprising a repertoire of nucleic acid sequences, each nucleic acid sequence encoding a part of variable domain of a heavy chain derived from an immunoglobulin naturally devoid of light chains, and wherein the library comprises approximately 10⁷ individual members with a high level of complexity.

NOTE that the instant claims are considered as the product-by-process claims in which the limitation 'cloned from a non-immunized source' is considered as process limitation.

Ghahroudi et al disclose single domain antibody fragments from camel heavy-chain antibodies (refers to instant claims 1 and 3). The reference discloses that the functional heavy chain immunoglobulins lacking light chain (refers to 'naturally devoid of light chains' of the instant claims) occur naturally in Camelidae. The reference discloses cloning repertoire of variable domains of heavy chain antibodies (i.e., see the abstract). The reference discloses that V_{HH} library displayed on phage particles was generated by immunizing a camel. The reference discloses that libraries containing the variable region repertoire of heavy chains from immunized camel blood lymphocytes were constructed. The reference discloses mRNA isolation from the lymphocytes and cDNA synthesis and cloning the CDR3 sequence (refers to 'at least a part of

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variable domain of heavy chain' of the instant claims) (i.e., see the materials and methods section). The reference teaches a total approximately 3×10^{11} phage were used in each round of panning (which refers to the limitation wherein the library comprises approximately 10^7 individual members with a high level of complexity).

The claimed invention differs from the prior art teachings by reciting 'cloned from non-immunized source'. However, the claimed expression library comprising repertoire of nucleic acid sequences encoding at least a part of a variable domain of a heavy chain naturally devoid of light chains, appear to be the same or obvious variations of the reference libraries, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific method of making the libraries of the instant versus the reference method, which would result in patentably distinct compounds. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed library is structurally and functionally different from the library of the reference, which uses a different method to synthesize the library. See in re Best 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

The instant claims are written as product-by-process claims. Even though the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability is based on the product itself. The patentability of a product does hot depend on its method of production. If the product in the product-by-process claims is same or as obvious from the product of the prior art, the claim is unpatentable Even

though the prior art product was made by a different process. "In re Thorpe, 777 F. 2d 695, 698, 227 U. S. P. Q. 964, 966 (Fed. Cir. 1985). (see MPEP 2113).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,399,763 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite that the library comprises 10⁷ individual members with a high level of complexity. The reference claims recite the same expression library of the instant claims

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comprising a repertoire of nucleic acid sequences, which sequences are not cloned from a source immunized with a target antigen, each nucleic acid encoding a heavy chain of immunoglobulin devoid of light chains, however do not recite the number of members in the library. The reference in example 1, discloses that the SfiI and PstI restriction sites, same as the instant method, such that a high complexity is achieved. And the reference teaches that the final libraries consisted of 6×10^{11} of individual clones. Thus, the reference claimed expression library is same as the instant claimed library.

19. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 20-26 of copending Application No. 10/122,434 or US20030078402 (PGPUB). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite that the library comprises 10⁷ individual members with a high level of complexity. The reference claims recite the same expression library of the instant claims comprising a repertoire of nucleic acid sequences, which sequences are not cloned from a source immunized with a target antigen, each nucleic acid encoding a heavy chain of immunoglobulin devoid of light chains, however the reference does not recite the number of members in the library. The reference in example 1, discloses the use of SfiI and PstI restriction sites, same as the instant method, such that a high complexity is achieved (see applicants response). And the reference teaches that the final libraries consisted of 6 x 10¹¹ of individual clones. Thus, the reference claimed expression library is same as the instant claimed library.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Response to Arguments

20. Applicant's arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

21. Applicant's arguments filed on 10/20/04 regarding the rejection of claims over Casterman references have been fully considered but they are not persuasive.

Applicants argue that neither of the references disclose or suggest a library as claimed, wherein the library comprises at least approximately 10⁷ individual members with a high level of complexity. Applicants arguments are not persuasive for the reasons addressed in the supra rejections.

Further, applicants refer to the specification page 14, line 8, 'it is disclosed that a second series of PCR products was obtained introducing a second type of restriction site, since the Psti restriction site in the first primer would theoretically also be present in 10 % of amplified fragment. Thus, to achieve a high level of complexity, the applicants used a combination of PCR primers with at least two different restriction sites so that no fragments were lost during the cloning process. Casterman does not suggest using more than one primer to avoid internal restriction sites.

Applicants' response and the specification citation have been considered and are not persuasive, since the instant claims are drawn to products and applicants seem to be arguing process limitations.

Applicant's arguments filed on 10/20/04, regarding the rejection of claims over Ghahroudi et al have been fully considered but they are not persuasive.

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Applicants argue that the reference does not disclose or suggest the applicants' library as claimed with the very high level of complexity resulting, in large part, from the applicants' use of nucleic acid sequence cloned from a non-immunized source.

Applicants' arguments have been fully considered and are not persuasive, since the 'high level of complexity' is not defined in the specification. And the term 'high level of complexity' is a relative term, and high level of complexity compared to what is not defined in the specification. Further applicants' arguments that the 'high level of complexity is generated from the use of nucleic acid sequence cloned from a non-immunized source' is not persuasive, since the instant claims are drawn to a product and applicants are referring to process limitations.

Applicants have not shown the libraries obtained from the instant specification disclosure or structurally distinct from the reference libraries. The rejections of record have been maintained for the reasons of record.

Conclusion

22. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PADMASHRI PONNALURI PRIMARY EXAMINER Padmashri Ponnaluri Primary Examiner Art Unit 1639

13 January 2005